REMARKS

Claim 32 has been amended to limit the average diameter range to the preferred range of former claim 33 (now cancelled) and to limit the packed bulk density range to the preferred range of former claim 34 (now cancelled).

Claims 33-35 and claims 42-47 have been cancelled.

Claims 32 and 36-41 remain in the patent application.

Claims 32-47 are rejected under 35 USC §102(b) as being anticipated by or under 35 USC § 103 as being obvious over US5,573,777 (Serpelloni et al.).

Applicants respectfully disagree.

As explained during the interview, pharmacists are concerned by the size of the pharmaceutical preparations intended to be swallowed, since many patients are very reluctant or experiment true difficulties to swallow drugs.

It is necessary, in order to have a good compliance with the prescribed treatments, to offer drugs to be swallowed which are as small as possible.

One aim of the present invention is thus to provide pharmacists with a conventionally used excipient for capsules, i.e. mannitol, which presents specific characteristics allowing an easy filling of capsules and above all the increase of the amount (weight) of mannitol that can be filled in a capsule of a given volume.

In order to comply with said criteria, the mannitol according to the invention presents:

- an average diameter of between 80 and 180 μm,
- a flow factor of at least 60, and
- a packed bulk density of between 0.70 and 0.80 g/ml.

The mannitol product described in Serpelloni et al. is obtained by atomization and is characterized by its friability, apparent density and granulometry, since it is intended to be used in tablets, but not by its packed density.

However, in example 1 of Serpelloni et al, a value of packed density is given: 549 g/l, i.e. 0.55 g/ml.

In the present patent application, mannitol according to Serpelloni et al. has been taken into consideration for comparison purposes (see last column of Table V, column 3 of Table VI "products produced by atomization") and it results from these comparison examples that mannitol according to Serpelloni cannot be satisfactorily used to fill capsules, since the amount of mannitol which can be introduced in a given capsule is too small, whereas a suitable filling is achieved with the mannitol according to the invention..

The Applicant acknowledges with appreciation that the Examiner was convinced by the Declaration under rule 132 and Test report enclosed with Applicant's letter dated April 7, 2003, for the specific values illustrated, packed bulk densities of 0.71 and 0.72 for average diameters of 126 and 178μm.

However, the Examiner indicated that the test was not commensurate in scope with the previously claimed range of 0.65-0.85 for packed bulk density and 60-200 μm for the average diameter.

The scope of the claims has now been drastically limited, the ranges being of 0.70 to 0.80 for packed bulk density and of 80 to 180 for average diameter.

The Applicant therefore considers that this objection is no longer founded since the Test report and the declaration under rule 132 correspond to said values.

As stated during the interview, since the results are convincing for the lower value of 0.70, they are a fortiori convincing for the upper value, i.e. 0.80. Indeed, the higher is the packed bulk density, the larger is the amount of mannitol which can be filled in a given volume.

Otherwise stated, the differences between a mannitol according to the invention presenting a packed bulk density of 0.80 and a mannitol according to Serpelloni et al. are necessarily greater than the differences between a mannitol according to the invention with a packed bulk density of 0.70 and a mannitol according to Serpelloni et al.

Claims 32 and 36-41 are thus patentable in view of Serpelloni et al.

In view of the above, it is considered that the application is now in proper form for allowance.

Favorable consideration and prompt allowance of these claims are respectfully requested.

Respectfully submitted,
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